K 053156

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CLEMENT CLARKE INTERNATIONAL

Precision by Tradition

510(k) Summary

Applicant: Clement Clarke Int. Ltd
Edinburgh Way
Harlow
Essex
CM20 2TT
United Kingdom

Establishment Registration No: 9610639

The product is manufactured at the above address

Contact: Mr Philip Hallybone (Quality/Regulatory affairs Manager)

Telephone: +44 (0)1279 414969
Fax +44 (0)1279 635232

Date of preparation: 01 November 2005

Proprietary Name: Mini-Wright Digital

Common Name: Peak Flow/FEV1 Meter (per 21 CFR section 868.1860)

Classification Name: METER, PEAK FLOW, SPIROMETRY

Medical speciality: Anaesthesiology

Classification: Class II (performance Standard – National Asthma Education Program's statement on technical standards for Peak Flow meters and the recommendations of the American Thoracic Society, Standardization of Spirometery 1994 Update)

Product code: 73 BZH

Equivalence: This device is substantially equivalent to the predicate device: OneFlow Tester, 510(k) K980951, class II

Indications for Use & Device Description

The Mini-Wright Digital is a handheld, battery operated, electronic Peak Flow Meter and FEV1 monitoring device with an internal memory capable of storing 240 sets of readings. This product will be sold as an OTC device with appropriate instructions. When used to monitor conditions such as asthma, this device should be used under the direction of a physician or licensed health care professional. The device is intended for use with paediatric and adult patients in both home and clinical settings.

Technological Differences with Predicate Device

The technological differences between the Mini-Wright Digital and the OneFlow Tester are

- Changes in design to incorporate smaller, more efficient, components such as the microprocessor and pressure sensor making the Mini Wright Digital smaller and requiring less power so that the battery does not need to be changed during the design life.
- The Mini Wright Digital is totally sealed so that it can be submerged in liquid for cleaning.
- The Mini Wright Digital can store 240 measurement results whereas the OneFlow Tester could only store 120 results.
- The Mini Wright Digital cannot be linked to a personal computer for the downloading of results for further analysis; this enabled the device to be totally sealed and a cost reduction. A diary sheet is provided with each device for the recording of measurements taken.

Performance Data

Non-clinical performance data has been compiled to support this application by testing the Mini-Wright Digital in accordance with the methods described in *the American Thoracic Society's document "Standardization of Spirometery" 1994 update*, and comparing the results with the limits for a monitoring device during evaluation.
Simulation of two years (design life) typical use has been performed and the difference between the accuracy / repeatability has been evaluated for values obtained before and after the simulation.

Conclusion From Testing & Evaluation

All tests undertaken where found to be within the stated recommendations for a monitoring device. Testing to simulate two years of use did not alter the accuracy or repeatability of the device.

Signed:..... Date Prepared: 01 November 2005
Mr P Hallybone
Quality/Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2006

Mr. Philip Hallybone
Quality/Regulatory Affairs Manager
Clement Clarke International, Limited
Edinburgh Way
Harlow, Essex CM20 2TT
UNITED KINGDOM

Re: K053156
Trade/Device Name: Mini-Wright Digital
Regulation Number: 868.1860
Regulation Name: Peak-Flow Meter for Spirometry
Regulatory Class: II
Product Code: BZH
Dated: November 4, 2005
Received: November 14, 2005

Dear Mr. Hallybone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

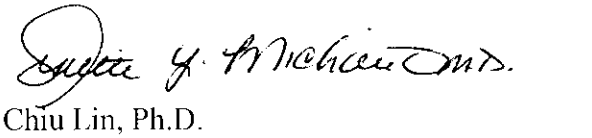
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K053156

Device Name: Mini-Wright Digital

Indications For Use:

The Mini-Wright Digital is a handheld, battery operated, electronic Peak Flow Meter and FEV1 monitoring device with an internal memory capable of storing 240 sets of readings. This product will be sold as an OTC device with appropriate instructions. When used to monitor conditions such as asthma, this device should be used under the direction of a physician or licensed health care professional. The device is intended for use with paediatric and adult patients in both home and clinical settings.

Prescription Use (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General Hospital, Infection Control, Dental Devices

K053156